EXHIBIT 36

Initial

interoffice
MEMORANDUM

EXHIBIT 4 3/17/06 KRANTZ

to: Nancy Ellery, Administrator

cc: Mary Dalton

from: Terry Krantz

re: Audit of Pharmacy acquisition cost by the Inspector General

date: October 5, 1995

On September 27th and 28th, the 11 states involved in the Pharmacy acquisition cost audit meet to discuss the preliminary results presented by the Office of the Inspector General. The purpose of this study was to determine the acquisition cost of legend pharmacy products through out the nation. Because of the variety of products and pricing methods, it was determined early in the study that of the results of the study would be presented as a discount from the average wholesale price (AWP). While AWP is a national standard it is apparent from the results of the survey that it has little to do with the acquisition cost of pharmacy products. The survey was segregated into different business classes such as urban and rural , independent and chain and non retail or specialized pharmacy in order to make the information more usable.

I have attached the study results which indicate the national average acquisition costs for brand products are estimated to be AWP -18.3 percent and for generic products they are estimated to be AWP - 42.45% . Montana's average discount as computed by the OIG is 16.23% and 48.46% respectively.

It is important to note that the study did not investigate the payment of these services by Medicaid only the cost of acquisition by the providers. All states involved are concerned that if these numbers are directly compared to the discounted AWP method of Medicaid Pharmacy pricing, confusion and questions will arise. The two major factors that must also be considered if

from the desk of...

Terry Krantz
Supervisor
Health Maintenance Section
Department of SRS
Helena, Montana, 59604

(406)444-4145
Fax: (406)444-1861

this comparison is done relate to the Dispensing fee portion of the payment formula and the effect of Federal upper limit (FUL) pricing for generic drugs. No work was performed by the OIG to determine how total reimbursement for pharmacy services relate to the cost of providing the service.

It is expected that when these results are published that the immediately concerns will be raised that pharmacy providers are being reimbursed more than the acquisition cost of the products and that changes should be made to change to pricing formula to increase the discount on AWP.. In order to address these concerns, states must do additional work to determine whether the cost to dispense is being accurately reimbursed and what affect the FUL pricing has on the discount for generic. In Montana we currently have a fairly good idea that the dispensing fee reimbursed is below the cost to dispense because of the cap on dispensing fees that is currently in place. Unfortunately, The FUL affect is not known at this time. The OIG has offered to release the base data so that FUL impact can be calculated by the states, but it is not expected to be received until after the findings are published. At that time , work could be performed to determine the impact of FUL on generic pricing.

All states involved also agreed that taking further discounts off of AWP in pricing formulas will result in a corresponding inflation to AWP to mitigate the impact. This might result in a cycle of action and reaction that results in increased administrative burden but little savings to Medicaid. Caution and careful thought should precede action in addressing this situation.

HCFA also presented the proposed rules relating to the rebate program. We are currently in the process of reviewing them.

NATIONWIDE SAMPLE RESULTS
BRAND AND GENERIC

APPENDIX _

	NATIONWIDE	SAMPLE UNIVERSE	SAMPLE SIZE	DRUG PRICES REVIEWED	POINT ESTIMATE	STANDARD ERROR	90 PERCENT CONFIDENCE LEVEL	
							LOWER LIMIT	UPPER LIMIT
BRAND	RURAL-CHAIN	1,095	73	5,723	17.40	1.05	15.67	19.13
	RURAL-INDEPENDENT	1,499	78	3,043	16.39	1.07	14.63	18.15
	URBAN-CHAIN	8,194	73	7,198	18.45	0.52	17.60	19.31
	URBAN-INDEPENDENT	6,242	91	3,009	18.71	0.90	17.22	20.19
	NON-TRADITIONAL	2,026	66	1,762	27.52	2.28	23.76	31.27
	OVERALL (EXCL. NON-TRAD)	17,030	315	18,973	18.30	0.66	17.21	19.38
GENERIC	RURAL-CHAIN	1,095	73	2,963	47.51	1.63	44.82	50.20
	RURAL-INDEPENDENT	1,499	78	1,798	47.38	0.93	45.85	48.92
	URBAN-CHAIN	8,194	72	2,634	37.61	2.82	32.97	42.26
	URBAN-INDEPENDENT	6,242	91	1,680	46.72	2.44	42.70	50.73
	NON-TRADITIONAL	2,026	59	1,262	57.70	1.98	54.43	60.96
	OVERALL (EXCL. NON-TRAD)	17,030	314	9,075	42.45	0.90	40.97	43.93

SAMPLE RESULTS BY STATE
BRAND NAME DRUGS

ST	CATEGORY	UNIVERSE	SAMPLE SIZE	DRUG PRICES REVIEWED	SAMPLE		90 PERCENT CONFIDENCE LEVEL	
					MEAN	STANDARD DEVIATION	LOWER LIMIT	UPPER LIMIT
CA	RURAL-CHAIN	109	6	427	16.45	2.82	14.61	18.29
	RURAL-INDEPENDENT	130	12	348	17.39	1.15	16.87	17.91
	URBAN-CHAIN	2,999	4	175	17.40	0.90	16.66	18.14
	URBAN-INDEPENDENT	2,621	7	161	17.63	1.45	16.73	18.53
	NON-TRADITIONAL	853	5	87	23.34	7.88	17.56	29.12
	OVERALL (EXCL. NON-TRAD)	5,859	29	1,111	17.48	0.34	16.93	18.04
DE	RURAL-CHAIN	22	9	700	17.18	2.84	15.98	18.38
	RURAL-INDEPENDENT	4	3	55	18.03	1.63	17.26	18.81
	URBAN-CHAIN	81	9	1,459	20.09	2.13	18.99	21.19
	URBAN-INDEPENDENT	18	8	315	18.26	0.66	17.98	18.55
	NON-TRADITIONAL	5	4	130	33.48	11.36	29.30	37.65
	OVERALL (EXCL. NON-TRAD)	125	29	2,529	19.25	0.45	18.50	19.99
DC	URBAN-CHAIN	74	3	185	18.33	3.86	14.75	21.92
	URBAN-INDEPENDENT	56	10	158	15.84	2.60	14.61	17.07
	NON-TRADITIONAL	3	1	117	20.90	0.00	20.90	20.90
	OVERALL (EXCL. NON-TRAD)	130	13	343	17.26	1.28	15.15	19.37
FL	RURAL-CHAIN	131	8	854	20.28	2.23	19.02	21.53
	RURAL-INDEPENDENT	85	8	320	17.23	0.60	16.89	17.56
	URBAN-CHAIN	1,848	11	1,310	19.43	2.18	18.35	20.51
	URBAN-INDEPENDENT	809	8	184	22.41	21.97	9.70	35.12
	NON-TRADITIONAL	436	5	49	31.72	16.51	19.65	43.79
	OVERALL (EXCL. NON-TRAD)	2,873	35	2,668	20.24	2.22	16.59	23.89
MD	RURAL-CHAIN	46	5	186	21.12	7.22	16.11	26.13
	RURAL-INDEPENDENT	39	10	356	20.05	4.40	18.08	22.02
	URBAN-CHAIN	521	4	511	18.63	1.19	17.65	19.60
	URBAN-INDEPENDENT	310	7	206	18.36	0.91	17.80	18.91
	NON-TRADITIONAL	143	7	140	20.33	6.15	16.60	24.06
	OVERALL (EXCL. NON-TRAD)	916	26	1,259	18.72	0.39	18.08	19.36

SAMPLE RESULTS BY STATE
BRAND NAME DRUGS

APPENDIX _
PAGE 2

ST	CATEGORY	UNIVERSE	SAMPLE SIZE	DRUG PRICES REVIEWED	SAMPLE MEAN	SAMPLE STANDARD DEVIATION	90 PERCENT CONFIDENCE LEVEL LOWER LIMIT	90 PERCENT CONFIDENCE LEVEL UPPER LIMIT
MO	RURAL-CHAIN	139	11	839	19.11	1.19	18.54	19.68
	RURAL-INDEPENDENT	227	8	498	18.45	0.70	18.05	18.85
	URBAN-CHAIN	359	9	856	18.29	1.82	17.30	19.27
	URBAN-INDEPENDENT	261	9	482	18.66	1.59	17.80	19.51
	NON-TRADITIONAL	135	9	271	32.79	15.32	24.67	40.90
	OVERALL (EXCL. NON-TRAD)	986	37	2,675	18.54	0.27	18.10	18.98
MT	RURAL-CHAIN	43	12	994	16.95	1.89	16.19	17.71
	RURAL-INDEPENDENT	118	10	412	15.65	3.09	14.11	17.19
	URBAN-CHAIN	23	11	1,092	17.45	2.22	16.65	18.24
	URBAN-INDEPENDENT	16	10	426	16.79	1.37	16.35	17.23
	NON-TRADITIONAL	45	11	400	28.03	8.41	24.40	31.65
	OVERALL (EXCL. NON-TRAD)	200	43	2,924	16.23	0.56	15.30	17.16
NE	RURAL-CHAIN	55	12	905	18.86	1.61	18.18	19.53
	RURAL-INDEPENDENT	241	11	523	19.17	2.61	17.91	20.44
	URBAN-CHAIN	105	9	786	17.30	2.64	15.92	18.68
	URBAN-INDEPENDENT	86	11	528	19.02	2.63	17.80	20.24
	NON-TRADITIONAL	198	5	129	32.24	14.90	21.42	43.06
	OVERALL (EXCL. NON-TRAD)	487	43	2,742	18.71	0.44	17.98	19.44
NJ	URBAN-CHAIN	817	5	247	19.54	1.76	18.25	20.83
	URBAN-INDEPENDENT	1,270	9	215	19.91	9.67	14.63	25.19
	OVERALL	2,087	14	462	19.77	1.98	16.51	23.02
NC	RURAL-CHAIN	379	5	251	14.90	6.82	9.91	19.89
	RURAL-INDEPENDENT	451	8	258	13.28	6.63	9.45	17.10
	URBAN-CHAIN	745	3	184	20.83	3.38	17.63	24.04
	URBAN-INDEPENDENT	502	6	154	15.85	7.36	10.94	20.76
	NON-TRADITIONAL	142	11	262	33.46	17.84	24.96	41.96
	OVERALL (EXCL. NON-TRAD)	2,077	22	847	16.90	1.25	14.84	18.97
VA	RURAL-CHAIN	171	5	567	18.64	0.93	17.97	19.31
	RURAL-INDEPENDENT	204	8	273	16.43	4.34	13.95	18.90
	URBAN-CHAIN	622	5	393	16.36	5.68	12.20	20.52
	URBAN-INDEPENDENT	293	6	180	18.83	4.49	15.85	21.82
	NON-TRADITIONAL	66	8	177	31.11	7.15	27.22	35.01
	OVERALL (EXCL. NON-TRAD)	1,290	24	1,413	17.23	1.31	15.08	19.39

SAMPLE RESULTS BY STATE
GENERIC DRUGS

ST	CATEGORY	UNIVERSE	SAMPLE SIZE	DRUG PRICES REVIEWED	SAMPLE MEAN	SAMPLE STANDARD DEVIATION	90 PERCENT CONFIDENCE LEVEL LOWER LIMIT	90 PERCENT CONFIDENCE LEVEL UPPER LIMIT
CA	RURAL-CHAIN	109	6	283	52.93	5.77	49.17	56.70
	RURAL-INDEPENDENT	130	12	178	53.54	9.16	49.40	57.69
	URBAN-CHAIN	2,999	4	34	31.85	20.72	14.82	48.88
	URBAN-INDEPENDENT	2,621	7	113	51.23	6.40	47.25	55.20
	NON-TRADITIONAL	853	4	52	56.35	10.82	47.47	65.23
	OVERALL (EXCL. NON-TRAD)	5,859	29	608	41.39	5.41	32.50	50.29
DE	RURAL-CHAIN	22	9	434	43.38	7.25	40.32	46.43
	RURAL-INDEPENDENT	4	3	29	41.33	27.07	28.48	54.19
	URBAN-CHAIN	81	9	345	34.48	7.39	30.66	38.30
	URBAN-INDEPENDENT	18	8	163	39.78	7.01	36.74	42.81
	NON-TRADITIONAL	5	4	92	63.85	7.91	60.94	66.76
	OVERALL (EXCL. NON-TRAD)	125	29	971	37.03	1.58	34.42	39.63
DC	URBAN-CHAIN	74	3	75	46.83	0.81	46.08	47.59
	URBAN-INDEPENDENT	56	10	81	39.79	13.97	33.20	46.38
	NON-TRADITIONAL	3	1	26	57.10	0.00	57.10	57.10
	OVERALL (EXCL. NON-TRAD)	130	13	156	43.80	1.74	40.93	46.67
FL	RURAL-CHAIN	131	8	250	41.90	6.82	38.06	45.74
	RURAL-INDEPENDENT	85	8	184	40.96	12.03	34.30	47.62
	URBAN-CHAIN	1,848	11	398	39.48	10.22	34.43	44.54
	URBAN-INDEPENDENT	809	8	189	45.96	9.31	40.58	51.35
	NON-TRADITIONAL	436	5	40	63.00	13.04	53.46	72.54
	OVERALL (EXCL. NON-TRAD)	2,873	35	1,021	41.46	2.19	37.86	45.06
MD	RURAL-CHAIN	46	5	241	39.08	12.97	30.07	48.09
	RURAL-INDEPENDENT	39	10	299	48.21	7.63	44.79	51.63
	URBAN-CHAIN	521	4	195	41.75	9.25	34.17	49.33
	URBAN-INDEPENDENT	310	7	88	41.73	14.07	33.08	50.38
	NON-TRADITIONAL	143	7	151	46.66	17.05	36.32	57.00
	OVERALL (EXCL. NON-TRAD)	916	26	823	41.88	3.18	36.65	47.12

SAMPLE RESULTS BY STATE
GENERIC DRUGS

ST	CATEGORY	UNIVERSE	SAMPLE SIZE	DRUG PRICES REVIEWED	SAMPLE MEAN	SAMPLE STANDARD DEVIATION	90 PERCENT CONFIDENCE LEVEL LOWER LIMIT	90 PERCENT CONFIDENCE LEVEL UPPER LIMIT
MO	RURAL-CHAIN	139	11	470	48.75	5.64	46.06	51.43
	RURAL-INDEPENDENT	227	8	256	44.34	6.93	40.38	48.30
	URBAN-CHAIN	359	9	329	48.36	6.66	44.75	51.96
	URBAN-INDEPENDENT	261	9	256	44.26	9.55	39.11	49.40
	NON-TRADITIONAL	135	7	205	57.34	10.17	51.18	63.50
	OVERALL (EXCL. NON-TRAD)	986	37	1,311	46.40	1.30	44.27	48.53
MT	RURAL-CHAIN	43	12	552	50.21	9.38	46.43	53.99
	RURAL-INDEPENDENT	118	10	213	48.28	7.89	44.35	52.21
	URBAN-CHAIN	23	11	662	48.35	8.43	45.33	51.38
	URBAN-INDEPENDENT	16	10	235	45.19	8.29	42.55	47.83
	NON-TRADITIONAL	45	11	284	61.95	12.72	56.47	67.44
	OVERALL (EXCL. NON-TRAD)	200	43	1,662	48.46	1.51	45.97	50.94
NE	RURAL-CHAIN	55	12	365	47.71	8.37	44.20	51.22
	RURAL-INDEPENDENT	241	11	286	47.26	10.67	42.09	52.43
	URBAN-CHAIN	105	9	221	34.41	5.97	31.28	37.54
	URBAN-INDEPENDENT	86	11	242	49.10	13.54	42.83	55.37
	NON-TRADITIONAL	198	5	98	63.18	12.49	54.11	72.25
	OVERALL (EXCL. NON-TRAD)	487	43	1,114	44.87	1.76	41.97	47.76
NJ	URBAN-CHAIN	817	4	92	41.70	12.26	31.64	51.76
	URBAN-INDEPENDENT	1,270	9	100	38.70	12.98	31.61	45.79
	OVERALL	2,087	13	192	39.87	3.55	34.03	45.72
NC	RURAL-CHAIN	379	5	162	49.54	14.31	39.08	60.00
	RURAL-INDEPENDENT	451	8	206	48.15	7.72	43.70	52.60
	URBAN-CHAIN	745	3	92	38.60	4.40	34.43	42.77
	URBAN-INDEPENDENT	502	6	71	48.92	12.36	40.67	57.17
	NON-TRADITIONAL	142	7	173	52.37	7.88	47.59	57.15
	OVERALL (EXCL. NON-TRAD)	2,077	22	531	45.16	2.00	41.88	48.45
VA	RURAL-CHAIN	171	5	206	44.90	13.35	35.22	54.58
	RURAL-INDEPENDENT	204	8	147	47.41	5.42	44.32	50.50
	URBAN-CHAIN	622	5	191	43.10	9.98	35.79	50.41
	URBAN-INDEPENDENT	293	6	142	48.03	14.85	38.16	57.90
	NON-TRADITIONAL	66	8	141	56.35	22.70	43.97	68.73
	OVERALL (EXCL. NON-TRAD)	1,290	24	686	45.14	2.67	40.74	49.54

EXHIBIT 37

29
2/22/06 Poulsen

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

February 28, 2000

Ms. Dorothy Poulson
Program Officer
Department of Public Health and
Human Services
Medicaid Services Bureau
P.O. Box 202951
Helena, Montana 59620-2951

Dear Ms. Poulson:

The Office of Inspector General (OIG), at the request of the Health Care Financing Administration, is requesting your assistance in a nationwide review of pharmacy and physician acquisition cost for prescription drugs reimbursed under the Medicaid program. The objective of the review is to develop an estimate of the difference between the actual acquisition cost and the average wholesale price and/or wholesale acquisition cost.

Montana was one of eight States randomly selected for this review. We plan to obtain invoices from 40 randomly selected pharmacy providers and 8 randomly selected physician providers in each State. Working through the State Pharmacy Administrators, we will request that the providers send copies of selected monthly invoices to the OIG by mail. With respect to the pharmacies, our review will distinguish between chain and independent, as well as rural and urban, providers.

We will contact you in the near future to discuss this review and determine a convenient time to meet with you at your location to establish the logistics of proceeding with this effort in your State.

We thank you in advance for your cooperation and assistance in this review. Please direct any questions to Paul Chesser of the OIG, Office of Audit Services, at 501-324-5127.

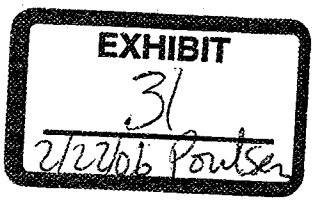
Sincerely,

George M. Reeb

George M. Reeb
Assistant Inspector General for
Health Care Financing Audits

MT 013790

EXHIBIT 38



Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF PHARMACY ACQUISITION COSTS FOR DRUGS REIMBURSED UNDER THE MEDICAID PRESCRIPTION DRUG PROGRAM OF THE MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

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AUGUST 2001

A-06-01-00005

MT 013731

SUMMARY

As a follow-up to our previous work, the Office of Inspector General (OIG) conducted a nationwide review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program. Since most States use Average Wholesale Price (AWP) minus a percentage discount, which varies by State, as a basis for reimbursing pharmacies for drug prescriptions, the objective of this review was to develop an estimate of the discount below AWP at which pharmacies purchase brand name and generic drugs.

To accomplish our objective, we selected a stratified random sample of 8 States from a universe of 48 States and the District of Columbia. Arizona was excluded from the universe of States because the Medicaid drug program is a demonstration project using prepaid capitation financing. Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid. Montana was one of the sample States selected, as well as Colorado, Florida, Indiana, Texas, Washington, West Virginia and Wisconsin.

In addition, a random sample of Medicaid provider pharmacies from each State was selected. The pharmacies were selected from each of five categories--rural-chain, rural-independent, urban-chain, urban-independent and non-traditional pharmacies (nursing home pharmacies, hospital pharmacies, home IV, etc.). We included the non-traditional category so as to be able to exclude those pharmacies from our overall estimates. We believed such pharmacies were able to purchase drugs at substantially greater discounts than retail pharmacies, and including them would have inflated our percentages.

We compared each invoice drug price to AWP for that drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. We then projected those differences to the universe of pharmacies in each category for each State and calculated an overall estimate for each State. Additionally, we projected the results from each State to estimate the nationwide difference between invoice price and AWP for each category.

In Montana, we obtained pricing information from 33 pharmacies. Specifically, we obtained 1,675 invoice prices for brand name drugs, and 915 invoice prices for generic drugs. For Montana, the overall estimate of the extent that invoice price was discounted below AWP was 19.71 percent for brand name drugs and 65.37 percent for generic drugs. The national estimates were 21.84 percent and 65.93 percent, respectively. Our previous estimates, based on CY 1994 pricing data, were 18.30 percent and 42.45 percent, respectively. The estimates combined the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain and urban-independent and excluded the results obtained from non-traditional pharmacies.

We are recommending that the Montana Department of Public Health and Human Services consider the results of this review as a factor in any future changes to pharmacy reimbursement for Medicaid drugs.

TABLE OF CONTENTS

INTRODUCTION

As a follow-up to our previous work, the Office of Inspector General (OIG) conducted a review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program of the Montana Department of Public Health and Human Services (State Agency). The objective of this review was to develop an estimate of the discount below AWP at which pharmacies purchase brand name and generic drugs. This review was conducted as a part of a nationwide review of pharmacy acquisition costs. Montana was 1 of 8 States randomly selected as part of the nationwide review.

BACKGROUND

Medicaid regulations provide for the reimbursement of drugs using two methods. If a drug is a multiple source (generic) drug, then reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public or an upper limit amount plus a dispensing fee. The Federal upper limit amounts are established by Centers for Medicare and Medicaid Services (CMS). If a drug is a single source (brand name) drug, or a generic drug for which an upper limit amount has not been established, then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or the estimated acquisition cost (EAC) plus a reasonable dispensing fee. The State agencies are responsible for determining the EAC and the dispensing fee.

The EAC for most States is calculated by using AWP for a drug less a percentage discount. The AWP is the price assigned to the drug by its manufacturer and is compiled by the **Red Book, First DataBank** and **Medi-Span** for use by the pharmaceutical community. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs. However, the OIG issued a report in 1984, which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP. In 1989, the OIG issued a follow-up report that found that pharmacies were purchasing drugs at discounts of 15.5 percent below AWP. Both the 1984 and 1989 reports combined brand name and generic drugs in calculating the percentage discounts and included a comparison of 3,469 and 4,723 purchases, respectively.

In 1989, CMS issued a revision to the State Medicaid Manual which pointed out that a preponderance of evidence demonstrated that AWP overstated prices that pharmacies actually paid for drugs by as much as 10 to 20 percent. The Manual issuance further provided that, absent valid documentation to the contrary, it would not be acceptable for a State to make reimbursements using AWP without a significant discount.

In 1997, the OIG issued separate reports on the actual acquisition cost of brand and generic drugs. The 1997 reports were based on comparisons of 18,973 invoice prices for brand products and 9,075 invoice prices for generic products. The report showed average discounts of 18.30 percent below AWP and 42.45 percent below AWP, respectively. Medicaid drug program expenditures in calendar year (CY) 1994 totaled about $9.4 billion. In CY 1999, nationwide expenditures for the program increased to about $17.9 billion. Montana reported Medicaid drug

expenditures of 49 million in CY 1999.

SCOPE

Our review was performed in accordance with generally accepted government auditing standards. The objective of our review was to develop an estimate of the difference between AWP and the actual invoice prices of both brand name and generic prescription drugs to Medicaid pharmacy providers. Our objective did not require that we identify or review any internal control systems

Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription such as therapeutic interventions, patient education, and physician consultation; and the cost of dispensing which includes costs for computers, multi-part labels, containers, technical staff, transaction fees, Medicaid specific administrative costs, and general overhead.

We obtained a listing of all Medicaid pharmacy providers from the State Agency. The State Agency was responsible for classifying each pharmacy as chain, independent or non-traditional. For purposes of this review, a chain was defined as four or more pharmacies with common ownership. We determined whether each pharmacy was rural or urban by comparing the county location for each pharmacy to a 1999 listing of metropolitan statistical areas and their components. We selected a stratified random sample of 40 pharmacies with 8 pharmacies selected from each of 5 strata--rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.) We included the non-traditional category so as to be able to exclude those pharmacies from our estimates. We believed that such pharmacies are able to purchase drugs at substantially greater discounts than a retail pharmacy and would have inflated our estimate.

We requested, from each pharmacy selected, the largest invoice from each different source of supply for a specified month in CY 1999. Supply sources include wholesalers, chain warehouse distribution centers, generic distributors, and manufacturers. Each pharmacy was initially assigned a month from January 1999 through December 1999 in order to provide a cross-section of this 12-month time period. However, we permitted some pharmacies to provide invoices from other months in 1999, as invoices were not available from the requested period.

We reviewed every line item on the invoices supplied by the sample pharmacies to ensure that the invoices contained the information necessary for our review. We eliminated over-the-counter items. Some invoices did not include National Drug Codes (NDC), which were needed to obtain AWP for the drug. We attempted to obtain NDCs in those instances. We used the **2000 Red Book**, a nationally recognized reference for drug product and pricing information, to obtain NDCs and identify over-the-counter items. Two prominent wholesalers, as well as four chain stores, whose invoices contained the wholesaler item number rather than NDCs, provided us with a listing that converted their item numbers to an NDCs. If we were unable to identify the NDC for a drug, we eliminated the drug.

To verify the drug name, we utilized the drug product file on the CMS web site. In addition to verifying the drug name, we were also able to determine the drug-type indicator from this file. The drug-type indicator showed whether the drug was a brand name or generic drug.

The State of Florida (FDB) provided us with a pricing file for the purpose of obtaining the AWP for each drug. We compared the invoice drug price to AWP for each drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. If a drug from an invoice was not on the pricing file we eliminated that drug.

Since some States also use wholesalers acquisition cost (WAC) in their reimbursement methodology, we also compared the invoice drug price to WAC for each drug for which WAC was available on the pricing file. We calculated the percentage, if any, by which WAC must be increased to equate the invoice price. The results of the WAC comparisons are reported in APPENDIX 3 and 4.

We used OIG statistical software to calculate all estimates as well as to generate all random numbers. We obtained the total number of pharmacies in the universe from the National Council for Prescription Drug Programs. We did not independently verify any information obtained from third party sources. Additionally, we did not attempt to identify any special discounts, rebates, or other types of special incentives not reflected on the invoices. Our review was conducted by our Little Rock, Arkansas Field Office from July 2000 through June 2001.

FINDINGS AND RECOMMENDATIONS

BRAND NAME DRUGS

We estimated that the invoice price for brand name drugs was 19.71 percent below AWP. The estimate combined all pharmacy categories except non-traditional pharmacies and was based on the comparison to AWP of 1,675 invoice prices received from 25 pharmacies. The standard deviation for this estimate was 0.39 percent (see Appendix 2).

The estimates by individual categories for brand name drugs are summarized in the following table:

Estimated Difference Between AWP and Invoice Price for Brand Name Drugs

Category	Estimate	Standard Deviation	Sample Pharmacies	Prices Compared
Rural-Chain	19.38	3.24	6	348
Rural-Independent	19.88	0.84	4	160
Urban-Chain	18.90	0.71	8	941
Urban-Independent	20.70	2.92	7	226
Non-Traditional	33.00	12.56	8	243
Overall (Exc. Non-Trad.)	19.71	0.39	25	1,675

GENERIC DRUGS

We estimated that the invoice price for generic drugs was 65.37 percent below AWP. Once again the estimate combined all pharmacy categories except non-traditional pharmacies. The estimate was based on the comparison to AWP of 915 invoice prices received from 25 pharmacies. The standard deviation for this estimate was 1.55 percent (see Appendix 2). The following table summarizes the results by category for generic drugs:

Estimated Difference Between AWP and Invoice Price for Generic Drugs

Category	Estimate	Standard Deviation	Sample Pharmacies	Prices Compared
Rural-Chain	59.28	13.23	6	195
Rural-Independent	67.03	3.86	4	76
Urban-Chain	66.76	2.67	8	536
Urban-Independent	69.37	3.97	7	108
Non-Traditional	69.00	9.25	8	164
Overall (Exc.Non-Trad)	65.37	1.55	25	915

CONCLUSIONS AND RECOMMENDATION

Based on our review, we have determined that there was a significant difference between AWP and pharmacy acquisition costs. The difference between AWP and pharmacy acquisition costs was significantly greater for generic drugs than for brand name drugs. We recognize that acquisition cost is just one factor in pharmacy reimbursement policy and that any change to that policy should also consider the other factors discussed in the Scope section of our report. Additionally, the effect of Federal upper limit amounts on generic drug reimbursements or usual and customary charge limitations should be taken into consideration. However, a change in any of the factors affecting pharmacy reimbursement could have a significant impact on expenditures because of the size of the program. We believe that the difference between AWP and pharmacy acquisition costs as determined by our review was significant enough to warrant consideration by the State in any evaluation of the drug program. Therefore, we recommend that the State Agency consider the results of this review in determining any future changes to pharmacy reimbursement for Medicaid drugs.

APPENDICES

SAMPLE DESCRIPTION

Sample Objectives:

Develop an estimate of the extent of the discount below Average Wholesale Prices (AWP) of actual invoice prices to Medicaid pharmacies in Montana for brand name drugs and for generic drugs.

Population:

The sampling population was pharmacy providers participating in the Medicaid prescription drug program of the State Agency.

Sampling Frame:

The sampling frame was a listing of all pharmacy providers participating in the Medicaid prescription drug program.

Sample Design:

A sample of 8 pharmacies was randomly selected from each of 5 strata. The 5 strata of pharmacies were rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.) Each pharmacy was assigned a month from 1999 for which to provide invoices. All pharmacies were initially assigned a month from January through December in a method designed to provide a cross-section of the twelve month period. However, some pharmacies were permitted to submit invoices from other months as invoices were not available for the month originally assigned. The largest invoice from each of four different sources of supply was requested. The sources of supply were identified as wholesalers, chain warehouse distribution centers, generic distributors, and direct manufacturer purchases. All invoice prices were compared to AWP.

Sample Size:

Eight pharmacies were selected from each stratum for a total of forty pharmacies.

Source of Random Numbers:

OAS statistical sampling software was used to generate the random numbers.

Characteristics to be Measured:

From our review of the pharmacy invoices, we calculated the percentage discount below AWP of actual invoice prices for all drugs on the invoices submitted.

Treatment of Missing Sample Items:

No spare was substituted for a pharmacy that did not provide information. If a pharmacy did not send an invoice for a particular type of supplier, we assumed that the pharmacy did not purchase drugs from that type of supplier during the month assigned to the pharmacy.

Estimation Methodology:

We used OAS Statistical Software to project the percentage difference between AWP and actual invoice prices for each stratum, as well as an overall percentage difference. The overall percentage difference excluded the non-traditional pharmacies. The projections were done separately for brand name drugs and generics.

Other Evidence:

We obtained AWP from a pricing file received from the State of Florida.

APPENDIX 2

MONTANA SAMPLE RESULTS

BRAND NAME DRUGS – AWP

Category	Universe	Sample Size	Prices	Sample		90 Percent Confidence Level	
				Mean	Standard Deviation	Lower Limit	Upper Limit
RURAL-CHAIN	57	6	348	19.38	3.24	17.33	21.44
RURAL-INDEPENDENT	104	4	160	19.88	0.84	19.20	20.55
URBAN-CHAIN	37	8	941	18.90	0.71	18.53	19.27
URBAN-INDEPENDENT	31	7	226	20.70	2.92	19.10	22.30
NON-TRADITIONAL	47	8	243	33.00	12.56	26.35	39.65
OVERALL (EXCL. NON-TRAD.)	229	25	1,675	19.71	0.39	19.07	20.34

GENERIC DRUGS – AWP

Category	Universe	Sample Size	Prices	Sample		90 Percent Confidence Level	
				Mean	Standard Deviation	Lower Limit	Upper Limit
RURAL-CHAIN	57	6	195	59.28	13.23	50.88	67.69
RURAL-INDEPENDENT	104	4	76	67.03	3.86	63.91	70.14
URBAN-CHAIN	37	8	536	66.76	2.67	65.39	68.14
URBAN-INDEPENDENT	31	7	108	69.37	3.97	67.20	71.54
NON-TRADITIONAL	47	8	164	69.00	9.25	64.10	73.90
OVERALL (EXCL. NON-TRAD.)	229	25	915	65.37	1.55	62.82	67.93

APPENDIX 3

NATIONWIDE SAMPLE RESULTS

BRAND NAME DRUGS – AWP				
Category	Sample Universe	Sample Size	Drug Prices Reviewed	Point Estimate
Rural-Chain	1,008	52	3,533	20.68
Rural-Independent	1,243	55	2,628	20.86
Urban-Chain	5,745	56	7,719	22.19
Urban-Independent	2,398	53	2,324	22.00
Non-Traditional	1,123	61	1,528	31.18
Overall (Excl. Non-Trad.)	10,394	216	16,204	21.84

GENERIC DRUGS – AWP				
Category	Sample Universe	Sample Size	Drug Prices Reviewed	Point Estimate
Rural-Chain	1,008	52	2,073	64.39
Rural-Independent	1,243	55	1,142	66.64
Urban-Chain	5,745	56	4,491	66.97
Urban-Independent	2,398	54	1,022	63.70
Non-Traditional	1,123	58	1,185	67.07
Overall (Excl. Non-Trad.)	10,394	217	8,728	65.93

EXHIBIT 39

DEPARTMENT OF
PUBLIC HEALTH AND HUMAN SERVICES
HEALTH POLICY & SERVICES DIVISION

JUDY MARTZ
GOVERNOR

GAIL GRAY, Ed.D.
DIRECTOR

STATE OF MONTANA

COGSWELL BLDG., 1400 BROADWAY
PO BOX 202951
HELENA, MONTANA 59620-2951

December 5, 2001

Gordon L. Sato
Regional Inspector General for Audit Services
Department of Health & Human Services
Office of Inspector General
1100 Commerce, room 6B6
Dallas, TX 75242-1027

Dear Gordon:

On November 16, 2001, Montana Medicaid received the draft report on the results of your review of pharmacy acquisition costs for drugs. After review of the findings, we agree that Montana should consider the results of this study as at least one factor in any future changes to pharmacy reimbursement for Medicaid drugs. Thank you for your efforts.

We appreciate your recognition of the fact that the review does contain some limitations, including: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription for instances such as therapeutic interventions; and the cost of dispensing which includes costs for supplies and staff.

However, we found another possible conflict in your method to verify the drug name. We have found that often, the drug product file maintained by Center for Medicare and Medicaid Services (CMS) may not be the same as First DataBank (FDB). Montana, along with many other states, uses the drug product file from FDB for pricing. Additionally, there are often discrepancies in how the drug is coded as a brand or generic. We have found situations when CMS may list a drug as a generic but FDB lists it as a brand.

Again, thank you for including Montana in the study. If you have any questions regarding this letter, please contact Shannon Marr, Medicaid Pharmacy Program Officer at 406-444-2738 or smarr@state.mt.us

Sincerely,

Maggie Bullock

Maggie Bullock, Administrator
Health Policy and Services Division

1.5.3

Cc: Jeff Buska
Shannon Marr

MT 013728

EXHIBIT 40

Montana Medicaid Values, Principles and Policy Goals

Given the diversity of groups directly impacted by the Medicaid program - recipients, providers, legislators, bureaucracy, and taxpayers – there are inevitably conflicting goals and priorities among the various groups. The purpose of establishing a common set of fundamental values and guiding principles for the Medicaid program is to provide an agreed on balance among competing goals and a framework within which policymakers can make rational and predictable adjustments to the program.

Establishment of a set of common values and principles also provides the foundation for development of specific public policy goals with corresponding objective measures of accountability.

Value: *Access*

Principle: As part of an overall health care system, Medicaid should insure access to a set of basic health care benefits for those Montana citizens most in need and most vulnerable.

Policy Implications:

1. Determination of the appropriate level of benefits necessary to meet the health care needs of the different populations Medicaid serves: Adults and children; the blind and disabled; and the elderly;
2. Given limited resources, establishing the balance between providing minimally adequate coverage to more people or extensive health care coverage to a smaller group;
3. Determination of the appropriate level of allowable income and resources for Medicaid eligibility and insuring equity in access to services across all programs;
4. Setting adequate provider reimbursement levels to insure recipient access to services without jeopardizing benefits or eligibility.

Value: *Personal Responsibility*

Principle: Medicaid should facilitate recipient responsibility for his or her own health care.

Policy Implications:

1. Incorporation of a set of meaningful incentives and consequences into the Medicaid program to encourage appropriate recipient use of the program;
2. Provide some degree of choice for recipients with regards to provider networks, delivery systems, e.g. fee for service, private insurance, cash and counseling;

3. Establish eligibility criteria in a manner that reasonably insures those who have the ability to contribute to their own health care expend their own resources prior to availing publicly funded health care programs;
4. Allow for participation by family members and care givers in development of treatment protocols.

Value: *Accountability*

Principle: The Medicaid system must be publicly accountable for quality of care and fiscal integrity.

Policy Implications:

1. Establish appropriate procedures and allocation of adequate resources to monitor quality of care;
2. Develop and maintain information systems that produce the necessary information and data to insure fiscal accountability;
3. Establish processes and procedures to allow timely and appropriate adjustments to the program to meet unanticipated budgetary shortfalls;

Value: *Diversity*

Principle: The Medicaid program must be responsive to the needs of different cultures, the geographic availability of resources, and severity of illnesses.

Policy Implications:

1. Develop programs that are sufficiently flexible to adapt to differences in availability of health care resources in different regions of the state;
2. Within the overall framework of the Medicaid program, develop programs that address the unique needs of the state's Native American urban and reservation populations;
3. Develop programs that equitably allocate resources across the diverse populations served by the Medicaid program, e.g. able bodied adult and child, developmentally disabled, mentally disabled, physically disabled, and elderly.

Value: *Public Participation*

Principle: As a publicly funded program, significant decisions regarding changes to the program must incorporate opportunities for broad public input and respect the opinions of all participants in the process.

Examples of Policy Implications:

1. Establish procedures to insure adequate public participation in significant policy decisions effecting the Medicaid program;
2. Determine an appropriate level of resources necessary to insure public participation and public education regarding the Medicaid program.

Policy Goal # 1: Facilitate access to a set of basic health care benefits for all Montana citizens with a priority for those most in need.	
Accountability Measures	1. Reduction in number of uninsured.
	2. Reduction in number of Medicaid recipients refused services.
	3. Increase in number of providers participating in Medicaid program.
	4. Adequacy of Reimbursement rates across all providers.
Policy Goal # 2: Create an environment where all recipients take an active role in their individual health care.	
Accountability Measures	1. Increased rate of participation in preventive health care activities.
	2. Degree of choice available to recipients.
	3. Increased collection rate of recipient cost sharing obligations.
	4. Reduced rate of fraudulent claims.
Policy Goal #3: The Medicaid program will be accountable for quality of care and fiscal integrity.	
Accountability Measures	1. Effectiveness in insuring healthy outcomes.
	2. Degree to which available services correspond with medical necessity.
	3. Availability of timely and accurate program level fiscal status reports.
Policy Goal #4: The Medicaid program will insure equity among various populations served by the program and be responsive to the needs of different cultures, geographic availability of resources and severity of illnesses.	
Accountability Measures	1. Degree to which Native American health care needs are being met relative to overall population.
	2. Degree to which requirements for patient compliance correspond with the capability of the individual to comply.
	3. Balance of resources allocation according to need.
	4. Reduced barriers related to socio-economic status.
Policy goal #5: The Medicaid program will include opportunities for broad public input into decisions that significantly change program design or populations served.	
Accountability Measures	1. Availability of timely and accurate information distributed in a variety of formats.
	2. Open and inclusive processes; transparent public policy decisions.

EXHIBIT 41

INQUIRY

DISPLAY SCREEN 1

NDC: 00003 1967 01

Previous NDC:
Replacement NDC:
Drug Term Date:

Last Batch Update: 070296 23:52:02:80
Last On-Line Update: 000000 00:00:00
User: 000

Drug Name: ZERIT 40MG CAPSULE Manufacturer: BMS ONCO/IMMUN

EXHIBIT 24 2/22/06 PortSer

Generic Code: 26714 Name: STAVUDINE
Ind: 2 SINGLE SOURCE Product Ind: 2 BRANDED DRUG
Generic Avail: N NO GENERIC AVAILABLE
Sex: B BOTH SEXES Age Minimum: 0 Maximum: 999

Desi Drug Indicator: 2 NON-DESI Effective Date: 040195

Therapeutic Classes Standard: 33 ANTIVIRALS Specific: W5B ANTVIR-HIV

---------- SPECIFIC THERAPEUTIC CLASS LIST ----------
W5B

PA1=RETURN PF2=SCREEN 2 PF3=SCREEN 3 PF4=SCREEN 4 PF5=SCREEN 5

AWP = 4.04562 = 242.74
Medicaid 3.641058 = 218.46
Dir Price 3.23650 = 194.19

Pharmacy's price = 196.91

MT 005418

EXHIBIT 42

Poulsen, Dorothy

From: David Shepherd [DShepher@dmas.state.va.us]
Sent: Friday, June 23, 2000 2:57 PM
To: NMPAAtalk@listbot.com
Subject: Re: [NMPAA-talk] NAMFCU Drug Pricing Issue

National Medicaid Pharmacy Administrators

Thank You - David Shepherd - Virginia

>>> Cody.C.Wiberg@state.mn.us 06/22/00 07:09PM >>>
National Medicaid Pharmacy Administrators

Greetings from Minnesota,

Thought I would share with you the text of e-mail that I sent to First DataBank last week:

"I am the Pharmacy Program Manager for the Minnesota Department of Human Services(DHS). As you are aware, First DataBank (FDB) has been working with representatives of state Medicaid Fraud Control Units on drug pricing issues. Since early May, FDB has been reporting to state Medicaid agencies "AWPs" for approximately 428 NDCs that are different than the real AWP that is being reported to your commercial customers. In Minnesota, pharmacy providers are usually reimbursed at AWP - 9% plus a dispensing fee. After checking local wholesale prices, I have discovered that the new "AWP" you are reporting to us is often at or below the actual acquistion cost (AAC) for which pharmacies can purchase the drugs. After subtracting an additional 9%, pharmacies will actually be reimbursed less than their cost for those products - even after adding back a dispensing fee. I have received a number of complaints from pharmacies about reimbursement. Those pharmacies have stated that they will stop supplying the products in question to our recipients if the new "AWPs" remain in effect.

In Minnesota, the reimbursement rate for drugs was established in statute by our legislature. While the legislators did not define AWP, we believe that their intent was to use "AWP" to mean a single estimate of wholesale price as published in a compendia such as Redbook or by First DataBank. My understanding is that FDB is now publishing two sets of "AWPs" for the 428 drugs in question - one for Medicaid agencies and one for everyone else.

The fact that the legislators chose to estimate actual acquistion cost at AWP - 9% indicates that they were aware that the single, published

AWP was actually higher than the price for which most pharmacies could buy drug products. Had they known that AWP would be reduced to AAC, they would not have established a 9% discount off of AWP.

Consequently, the Minnesota Department of Human Services has determined that we must use the AWPs that FDB is reporting to its commercial customers and NOT the "AWPs" that you are currently reporting to us for the 428 drugs in question. DHS staff intends to bring this issue to the attention of our legislature during the next scheduled session. But for now, I am formally requesting that First DataBank supplies the Minnesota Department of Human Services with the AWPs it supplies to other commercial, non-Medicaid customers as soon as possible. Please feel free to contact me with any questions or concerns."

First DataBank contacted me today and confirmed that they will honor this request. Like many of you, I have spent a considerable amount of time on this issue. (I even spent half of one Sunday in a pharmacy verifying their actual acquisition cost for over one hundred of the drugs in question. For almost all of those drugs AAC was at or above the new "AWP"). A number of pharmacy providers, ranging from independents to chains to specialty infusion pharmacies have written or called to complain. Many of them called about specific drugs after realizing that they were being reimbursed at less than cost.

There is no doubt in my mind that NAMFCU is correct when it points out that the spread between AWP and AAC is too large for many, even most, of these drugs. The question is - what should be done about it? Almost everyone who is familiar with pharmacy reimbursement knows that AWP "Ain't What's Paid". That's why most states and private pharmacy benefit managers reimburse pharmacies at AWP minus a discount (anywhere from 5-15% or more). It is also one reason why there is a federal upper limit list and why many states and private PBMs have maximum allowable cost programs. The spread between AAC and AWP is taken into account when determining what to pay for a dispensing fee. For drugs not on the FUL, 42CFR447.331(b) states:

"b) Other drugs. The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under Sec. 447.332 must not exceed in the aggregate, payment levels that the agency has determined by applying the lower of the-- (1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or (2) Providers' usual and customary charges to the general public".

Some public and private third party payers have purposely kept the dispensing fee low precisely because there is a spread between AWP and AAC. In fact, when pharmacy organizations have sought an increase in dispensing fees, the AWP spread has been pointed out to legislators. It is true that ingredient reimbursement is supposed to be based on estimated acquistion cost. The ancillary costs of dispensing the drug are supposed to be accounted for by the dispensing fee. If the AWP spread disappears, the dispensing fee may have to be increased, especially for many of the 428 drugs currently in question. Many of these drugs require some type of compounding or other preparation.

The point, I guess, is that NAMFCU's solution is really a substantial change that may very well have a negative impact on pharmacy providers and, even more importantly, patients. In Minnesota, we believe that something should be done about the AWP spread. However, the problem should be approached in one of two ways:

1. State Medicaid agencies should be allowed to work out their own solutions (by increasing the discount off of AWP, adjusting the dispensing fee, establishing MACs, etc); or
2. A national solution should be pursued that accounts for all aspects of the problem and that is developed by and with input from all interested parties (NAMFCU, HCFA, state Medicaid agencies, private third party payers, First DataBank, pharmacy organizations, etc).

Cody Wiberg, Pharm.D., R.Ph.
Pharmacy Program Manager
Minnesota Department of Human Services

(651) 296-8515
(651) 282-6744 (FAX)

To unsubscribe, write to NMPAAtalk-unsubscribe@listbot.com